UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CAROL LEWIS, Plaintiff, v. THOMAS E. PRICE, Secretary of the United States Department of Health, and Human Services, Defendant.	Civil Action No.: **1:15-CV-13530-NMG**

PLAINTIFF'S OPPOSITION TO HHS' MOTION TO AFFIRM HHS' DECISION AND REPLY TO DEFENDANT'S OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGEMENT

Plaintiff Carol Lewis requests that the Court grant her Motion for Summary Judgement and deny HHS' Motion to Affirm HHS' Decision, for the reasons set forth below.

I. INTRODUCTION

The Secretary asks this Court to ignore Congress' and the Secretary's long-standing broad interpretation of the Durable Medical Equipment ("DME") Medicare benefit, to ignore the overwhelming evidence in the administrative record ("AR") that a continuous glucose monitor ("CGM") is the primary and essential medical device by which individuals with Type 1 diabetes ("T1D") control their diabetes, and to ignore this Court's and other District Court's findings with respect to the legal significance of a Medicare contractor's informal communications. The Secretary urges this Court to ignore his more than 40 final decisions, including at least two

decisions rendered on Ms. Lewis' claims for CGM supplies, finding that a continuous glucose monitor is covered under the Medicare DME benefit and is reasonable and medically necessary for individuals with T1D. The Secretary attempts to argue the novel proposition that medical equipment that is FDA-approved as adjunctive to another more limited monitoring method, does not serve a primary medical purpose. The Secretary's Decision is not supported by substantial evidence and is contrary to the law and facts.

The gravamen of the Secretary's argument that because Ms. Lewis' CGM FDA label indicated that users should conduct a confirmatory finger stick before altering insulin, her CGM does not primarily and customarily serve a medical purpose. The Secretary's logic is fundamentally flawed and belied by the evidence: (1) nothing in the Medicare statute, regulations or the Secretary's long-standing and historic interpretation of the DME benefit indicates that adjunctive medical devices are not primarily medical devices; (2) a CGM provides medical information for the management of diabetes that no other medical device provides and which is necessary for the management of diabetes; and (3) supported by the peer-reviewed literature and because CGM had become as precise as finger sticks, before the FDA's regulatory acknowledgement, the standard of care had evolved such that Medicare beneficiaries have been using CGM to make insulin adjustments without a confirmatory finger stick.

Further, because no evidence in the AR supports a finding that CGM is not primarily a medical device, the Secretary asks this Court to rely on (1) a bald statement in a discredited informal communication issued by a Medicare contractor and which this Court already determined does not constitute Medicare coverage guidance; or (2) a recent statement that explicitly states should not be applied. The Secretary urges the Court to ignore its own ruling

and the Secretary's numerous final rulings, before and after the decision at issue, finding that CGM is DME covered by Medicare for individuals suffering from T1D.

A. CGM is the Primary and Essential Means by Which Type 1 Diabetics and Their Doctors Manage Type 1 Diabetes

Other than his unsupported and illogical assertion that a CGM is not primarily and customarily considered a medical device, the Secretary concedes that a CGM otherwise satisfies the DME regulatory criteria. The Secretary's assertion that a CGM does not primarily perform a medical purpose is belied by the customary use of CGM and his longstanding recognition that adjunctive medical devices can primarily serve a medical purpose.

The Secretary concedes no definition exists for "precautionary," but provides an exemplar of a preset backup oxygen tank. The undisputed evidence is that a CGM is the primary means by which Type 1 diabetics control their diabetes, and finger sticks simply serve a confirmatory function. Individuals are prescribed a CGM precisely because they have not been able to control their diabetes with finger sticks, i.e., finger stick testing does not meet their medical needs. Because Ms. Lewis has hypoglycemic unawareness, i.e., she has no physical warnings of an impending glucose low, without a CGM, Ms. Lewis cannot know when to conduct a finger stick or take any corrective action.[1] A CGM is the primary, essential means by which such diabetics control their diabetes – it is not a backup.

Further, although a finger stick can provide a "snapshot" of glucose at a point in time, a CGM provides a "video" showing where glucose is, where it has been, and a prediction of where it is going, and how quickly it is going. Patients (and their caregivers) use this information to make immediate insulin decisions, and clinicians use this information for the long-term

[1] For example, Ms. Lewis will not wake to conduct a finger stick if a fatal low occurs while she is sleeping, the unfortunate fate of approximately one of twenty individuals with T1D each year.

management of diabetes. Finger sticks cannot provide this medical information which is essential to provide the standard of care for individuals suffering from T1D. The Secretary cannot and does not dispute that all the relevant medical societies recognize CGM as a medical device that is medically necessary and is the standard of care treatment for T1D.[2] For such diabetics, a CGM can only be considered "precautionary" if it is "precautionary" to avoid death.[3]

Finally, long before the FDA acknowledged that post-2012 CGM versions are so precise that confirmatory finger sticks are unnecessary, the peer-reviewed literature and medical practice standards recognized that not-withstanding the FDA label, the vast majority of CGM users made insulin adjustments based solely on CGM readings, and CGM users had superior control of their diabetes. Less than 12% of CGM users report always confirming a reading with a finger stick.[4]

B. An Adjunctive FDA Label Does Not Deprive a Medical Device of a Primary Medical Purpose

The Secretary asserts a novel position that a CGM does not primarily serve a medical purpose because it is adjunctive to a finger stick glucose monitor. This position is belied through a cursory review of NCD 280.1, a partial list of deemed DME, that reflects Medicare coverage of "augmentative" or "adjunctive" devices: continuous passive motion devices (DME used as an adjunct to physical therapy following surgery); oxygen humidifiers (an adjunct to home oxygen machines, another DME device); muscle stimulators, augmentative and communication devices. As if to underscore the absurdity of his current position, in NCD 280.1, the Secretary recognizes

[2] The Secretary cites a 10 year old paper for the proposition that the medical societies recognize CGM as an adjunctive device because it was not as accurate as a finger stick. Sec. Mtn. at 16. The Secretary ignores the accuracy of current CGMs which has been recognized by medical societies and the FDA. As described below, regardless of its adjunctive status, a CGM is a primary and essential medical device for the management of T1D.

[3] A CGM will not simply allow Ms. Lewis to detect a low "more quickly" as the Secretary suggests (Sec. Mtn at 11), she cannot detect potentially fatal lows without a CGM. Again, the life expectancy for an individual diagnosed with T1D between 1950 and 1965 was 53.4 years.

[4] See https://myglu.org/articles/power-to-the-people-how-the-voice-of-people-with-t1d-can-influence-regulatory-decisions. This stems in part from the practical reality that many do not have timely access to finger stick supplies, facilities to wash hands, and the ability safely and appropriately dispose of the waste products.

the primary medical purpose, and covers as DME, a self-contained pacemaker monitor that ensures that a pacemaker is functioning properly, i.e., Medicare covers a medical device whose sole function is to ensure the proper functioning of another medical device.

His position is further belied by a cursory review of his numerous coverage decisions extending Medicare coverage to other "adjunctive" devices and medications. See e.g., NCD 10.2 ("TENS may be covered whether used as an adjunct to the use of drugs, or as an alternative to drugs, in the treatment of acute pain resulting from surgery"); NCD 20.29 ("the use of [hyperbaric oxygen] therapy is covered as adjunctive therapy"); NCD 270.1 ("The use of ES and electromagnetic therapy for the treatment of wounds are considered adjunctive therapies, and will only be covered for chronic . . . diabetic ulcers, and venous stasis ulcers."); NCD 150.2 (covering a bone stimulator to augment bone repair following surgery).

The Secretary acknowledges the medical purpose of numerous medical monitors (including heart monitors, respiratory monitors, oxygen saturation monitors), and covers them under Medicare. Further, the Secretary did not dispute, and thus admits, that he recognizes the primarily medical purpose and medical necessity of numerous medical tests that are confirmed by subsequent tests or that direct additional testing. Medicare covers both the first "presumptive" test and the secondary confirmatory test. Indeed, Medicare covers entire classes of medical tests that are performed solely on the basis of the results of a first Medicare-covered test, i.e., reflex testing.

Thus, the Secretary has recognized, through NCD 280.1 and numerous national coverage policies, the primary medical purpose of numerous devices that serve an adjunctive purpose and qualify for coverage under the DME benefit. Further, the Secretary does not deny and has

extended Medicare coverage to numerous medical monitors and numerous laboratory tests that prompt secondary testing. A CGM's adjunctive FDA approval did not and does not deprive a CGM of its primary and customary medical purpose. Indeed, the Secretary concedes that a CGM is only useful to individuals who have diabetes and it is used to manage that medical condition, i.e., it has no application outside of a medical context.

C. An Unsupported and Discredited Statement Is Not Substantial Evidence That Supports the Secretary's Decision

The "substantial evidence," indeed the only evidence, the Secretary relies on in support of his Decision is the discredited statement in the NHIC Article. [5] Despite the overwhelming evidence in the AR that demonstrates a CGM primarily and customarily serves a medical purpose, the Secretary urges this Court to uphold his Decision based on "the logic" in the Article. Unfortunately, the Article contains no "logic" – simply a bare assertion that is contrary to all the peer reviewed literature, medical consensus statements, technology assessments, private insurance companies' determinations, and the standard of care in the medical community.

The Secretary concedes that if an item is never covered, he requires the MACs to issue an LCD advising Medicare beneficiaries and providers of that determination. Sec. Mtn at 6. It is undisputed that the MAC did not issue an LCD indicating CGMs are not covered. The Secretary concedes the LCD did not incorporate the Article. Nonetheless, the Secretary argues the Article provides guidance and rationale, ignoring this Court's ruling that Articles do not provide Medicare coverage guidance[6] and that the Article's assertion that CGM is simply precautionary,

[5] Contrary to the Secretary's assertions, the Council did not rely on NCD 40.2 and LCD 11530/33822 – the Secretary claimed they did not apply although on their face they appear to extend coverage to a CGM.
[6] See *Finigan v. Burwell*, 2016 WL 2930905 (D. Mass, May 19, 2016). The Secretary cited MPIM, Ch. 13, §13.1.3 for the proposition that articles contain benefit category determinations or statutory exclusion provisions. The citation, however, states all coverage decisions should be in an LCD and articles contain coding and billing instructions.

has been deemed invalid under the reasonableness standard, based on a review of the publications, consensus statements, technology assessments, and evidence of widespread adoption of CGM throughout the medical community, i.e., the very documents that exist in the AR in this case.[7]

Although neither the NCD 280.1 nor LCD L11530/L33822 indicate that a glucose monitor that uses an indirect method to measure glucose is excluded from coverage (indeed NCD 280.1 indicates a glucose monitor will be covered if a Medicare beneficiary meets the criteria in NCD 40.2), the Secretary urges this Court to ignore Congress' intent, and his own policies, that the DME benefit be construed broadly. Further, the Secretary's position in this case requires the Court to ignore the more than 40 final decisions[8] the Secretary issued finding that CGM primarily serves a medical purpose, fits within the DME benefit, and is reasonable and medically necessary for T1D. If a CGM was statutorily excluded, as the Secretary now argues, the Secretary could not have issued more than 40 final decisions finding the obverse.[9]

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[7] The Secretary urges this Court to ignore the ruling of the Civil Remedies Division on the basis CMS appealed it. However, based on Ruling 1682-R, the MAC is required to amend the Article, although the MAC has not despite the passage of two months, and the procedural implications for the LCD challenge are unclear. Under Medicare regulations, "Revising an LCD under review to remove the LCD provision in question has the same effect as a decision" that the provision was invalid under the reasonableness standard. See 42 C.F.R. §§426.478, 426.420(b), 426.460(b), 426.476(d). Thus, the MAC's failure to make an appropriate amendment to the Article based on Ruling 1682-R should not redound to Ms. Lewis' detriment. Regardless of the foregoing, the review of the ALJ decision is limited to whether the ALJ decision contains a material error with respect to application of the reasonableness standard, and not findings of fact. Thus, regardless of the future procedural effect of Ruling 1682-R on the LCD challenge, the substantive review of the evidence, which mirrors the evidence in this case, resulted in a determination that statement that CGM is precautionary is invalid under the reasonableness standard. Indeed, the documentary evidence was so overwhelming that the judge declined to take proffered testimonial evidence.

[8] See e.g., http://www.ajmc.com/journals/evidence-based-diabetes-management/2016/May-2016/A-Medicare-Appeal-for-CGM-Coverage-One-Patients-Never-Ending-Story; https://myglu.org/articles/persistence-triumphs-getting-medicare-to-cover-my-cgm. The Secretary does not deny he has issued numerous favorable decisions. Nothing precludes this Court from considering publically available information regarding the Secretary's prior and subsequent inconsistent rulings. See e.g., *Bloom v. Sebelius*, 5:16-cv-00121-gwc (DC Vt., filed Apr. 29, 2016), Dkt. 1 at 14 (referencing two favorable ALJ decisions before Ms. Lewis' unfavorable decision).

[9] In addition to issuing an NCD to preclude the issuance of an ALJ decision that is contrary to the law, the Secretary and his contractors can use the referral process to correct an ALJ decision that is contrary to the law. See 42 C.F.R. § 405.1110(b). The Secretary, however, has allowed more than 40 final decisions to issue finding Medicare covers CGM.

Indeed, because Ms. Lewis and other Medicare beneficiaries received final favorable decisions before and after Ms. Lewis received the unfavorable administrative law judge ("ALJ") decision that is the subject of this complaint, Ms. Lewis filed a challenge to the policy statement that CGM is precautionary. Ms. Lewis sought to end the Secretary's arbitrary and capricious findings with respect to whether CGM was a Medicare benefit, and the Sisyphus effort[10] that recurred each month Ms. Lewis and other Medicare beneficiaries received denials of Medicare coverage of CGM supplies.[11] Ms. Lewis prevailed in that effort and the policy that CGM is precautionary was deemed invalid.

When no LCD or NCD exists, Medicare contractors make coverage determinations based on individual consideration. See Sec. Mtn at 6. In making those determinations, the MACs are required to base those decisions on the peer-reviewed literature and consensus of medical experts. MPIM Ch. 13, §13.7.1. Again, the peer-reviewed literature, the consensus of medical opinion, technology assessments, and the determinations of private payers, all support Medicare coverage of CGM as medically necessary. Further, because the cost to the Medicare system from just one emergency room or EMT visit from an undetected glucose low exceeds the annual cost of a CGM, it has been deemed reasonable. CGM not only satisfies the statutory definition of DME, but it is reasonable and medically necessary as the Secretary repeatedly has found.

In short, the Secretary routinely has recognized as DME, medical devices that are FDA cleared for an adjunctive medical purpose, and has recognized the primarily medical nature of

[10] By regulation, neither an ALJ nor Medicare Appeals Council decision is precedent. 42 C.F.R §405.1062(b); 74 Fed. Reg. 65327 (Dec. 9, 2009). Thus, despite winning multiple ALJ decisions, Medicare beneficiaries, who typically are elderly and are battling a serious illness, must repeatedly endure a multi-step, multi-year process to secure coverage for this medically necessary device.

[11] Ms. Lewis has reached the ALJ level six times winning Medicare coverage in a majority of the finally decided cases. See e.g., ALJ Appeal Nos. 1-4562067999, 1-3248004876, 1-5093258404. Another Medicare beneficiary has reached the ALJ level ten times, again securing favorable final decisions the majority of times – decisions which found CGM is DME and covered by Medicare. See *Bloom*, Dkt. 23 at 1.

various devices that provide adjunctive treatment. No basis exists for asserting a medical device does not primarily serve a medical purpose because it is adjunctive. The Secretary asks this Court to ignore the overwhelming evidence in the AR that CGM is recognized by the medical community (nationally and internationally) and commercial payers, as the primary means by which brittle diabetics control their diabetes and without which they could suffer serious medical consequences, his more than 40 final decisions finding CGM to be covered, and the Civil Remedies Division decision that the assertion that CGM is precautionary is invalid under the reasonableness standard.

Because nothing in the AR supports his position, the Secretary asks the Court to consider a recently issued document that is neither an NCD nor an LCD, and which explicitly states should not be applied to this case - CMS Ruling 1682-R. Nonetheless, because nothing in the AR supports the Decision, the Secretary suggests it might be "illuminating." Ruling 1682-R acknowledges that a CGM serves three medical purposes: (1) providing glucose trend information that can be used by clinicians to develop long term management plans for individuals suffering from diabetes and for diabetics to use for the immediate management of diabetes; (2) aiding in the detection of hypoglycemic lows and hyperglycemic highs; and, in some cases, (3) replacing blood finger stick monitoring. The fact that all CGMs do not replace finger sticks does not negate the other medical purposes that all CGMs provide - trend and unexpected low detection – medical purposes no finger stick can provide. Indeed, Ruling 1682-R is so recent, the validity of its novel assertion that regardless of the unique, essential medical

purposes a medical device serves, if it requires confirmation for one purpose it cannot be deemed primarily medical, has not been implemented or tested.[12]

D. The Standard of Review

The Secretary's Decision must be supported by substantial evidence, which review requires the Court to consider the entire AR. See Pl. Mtn. at 12. The deference accorded is reduced when the evidence shows the Secretary did not consult with appropriate sources and adequately substantiate his decision, and in further view of the lack of consistency. In this matter, not only is the Secretary's Decision not supported by substantial evidence, it is arbitrary and capricious in view of his other final decisions finding Medicare coverage of CGM for indistinguishable Medicare beneficiaries and even claims for the same beneficiary, and his numerous policies extending coverage to "adjunctive" DME.[13]

II. CONCLUSION

The Secretary's denial of Ms. Lewis' CGM claims is inconsistent with the peer-reviewed literature, the consensus of the medical and payer communities, independent assessments, and the Secretary's more than 40 final determinations that CGM is covered under the DME benefit and is reasonable and medically necessary. The Secretary's Decision is not only not supported by substantial evidence, it is refuted by overwhelming evidence, arbitrary and capricious, and not in accordance with law. For the foregoing reasons, this Court should grant Plaintiff Lewis' Motion for Summary Judgment and deny HHS' Motion to Affirm HHS' Decision.

[12] Notwithstanding Ruling 1682-R which mandates coverage of at least some CGM, the relevant Medicare contractor has not altered its Article or its "logic." Indeed, Ms. Lewis currently uses a Dexcom G5, a CGM that would be covered under Ruling 1682-R.

[13] Contrary to the Secretary's assertion, Ms. Lewis did not advocate that the standard of review is arbitrary and capricious. See Pl. Mtn at 11-12.

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Respectfully submitted,
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